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NATIONAL WOMEN'S HEALTH NETWORK

Food and Drug Administration
Public Hearing on
Over-the-Counter Drug Products
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Comments of
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Good afternoon. My name is Amy Allina. I am the Program & Policy Director of the National Women's Health Network, a non-profit women's health advocacy organization. The Network is supported by more than 10,000 individual and 300 organizational members and we accept no financial support from pharmaceutical companies or medical device manufacturers.

I am pleased today to have the opportunity to provide our perspective to CDER as you consider the agency's approach to regulating over-the-counter (OTC) drug products. In the 25 years since the Network was founded, we have spoken at a number of FDA meetings called to consider whether a specific drug should be made available over-the-counter. Sometimes we have supported the shift; and sometimes we have opposed it.

Just as we know that the agency is striving for a consistent set of standards to use in making these determinations, we have tried to be consistent in the positions we have taken. We share with the agency the concern that OTC products must have a low incidence of adverse reactions or significant side effects and a low potential for harm from misuse. And they must also be intended for use in conditions that can be readily recognized by a consumer without the assistance of a clinician.

Another very important consideration for the Network is the accessibility of sufficient, accurate and unbiased information for consumers about a product to ensure that we can make an informed decision about whether to take a drug. The importance of this factor is underlined by our belief that the company selling a drug product will not make an unbiased judgement about what information should be conveyed to women or how best to convey it. While there is no guarantee that the clinician who prescribes a drug will convey the appropriate information about the prescription product, the FDA's responsibility for ensuring that this happens is even higher with an over-the-counter product.

My comments today will address a number of specific types of products as well some of the more general issues relating to consumer understanding and to the structure of the regulatory system.

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Classes of Products

- *Microbicides*: The level of STD infection in the United States is unacceptably and unnecessarily high. Women now constitute 23 percent of all AIDS cases here, and the CDC estimates that 75 percent of HIV infected women in this country were infected through heterosexual contact. The Network is strongly committed to the development of topical microbicide products which women will be able to use to protect themselves against STD and HIV infection. We believe that in order for microbicide products to be used widely and effectively, there will have to be some that are available without prescription. There is currently a range of products in development, some of which are likely to be appropriate for approval for over-the-counter distribution; others, however, may need to start as prescription products.

  While the safety standard for OTC distribution should not vary from product to product, some microbicides will be able to meet that standard more easily and/or quickly than others. Those products which have already been approved for other uses (and therefore have an established safety record) are likely to be able to demonstrate sufficient safety for OTC distribution more easily than products which are entirely new. Based on our understanding of the microbicides in development, we suggest that the FDA might consider microbicide products in four tiers:

  1) products with an established safety record in vaginal/rectal use;
  2) products with an established safety record in use in contact with other mucosal tissue;
  3) products with an established safety record in topical use (on non-mucosal tissue); and
  4) new chemical entities.

- *Oral Contraceptive Pills*: While the Network would like to see more OTC contraceptive options made available to women, we oppose the OTC distribution of oral contraceptive pills for continuing, regular contraception. We believe that prescription status for regular oral contraceptives is necessary to maintain effective use of this method and to protect the health of women who choose to use it.

  Experience in Sweden and other countries has demonstrated that when the Pill is distributed with no counseling and no opportunity for dialogue about the method, effective use declines. In addition, we have concerns about the health impact of OTC distribution of oral contraceptive pills. Without a prescription requirement:

- there will be no opportunity for a health care provider to screen out users who should not be taking oral contraceptives over the long-term; and
- the opportunity for preventive health care and disease detection will be lost, which is of particular concern when it comes to women of color and low-income women who are already likely to have decreased access to such health services

If a third alternative between the current prescription status and OTC distribution were available in the United States, such as distribution by pharmacists from behind the counter, the Network would support distribution of oral contraceptives in that way.

- *Emergency Contraceptive Pills*: The Network strongly supports the distribution of emergency contraceptive pills by pharmacists as is being done in Washington state under collaborative practice agreements with physicians. If behind the counter status was an option in the United States, the Network would support making emergency contraceptive pills available in that way.

In addition, the Network believes that the medical, political and economic issues raised by emergency contraceptive pills are different from those associated with the on-going use of oral contraceptives. Recognizing that there are communities where even pharmacist distribution will not resolve the barriers that currently prevent women have having timely access to the method, the Network would support over-the-counter distribution of emergency contraceptive pills under the following conditions:

- there must be appropriate label warnings to protect the health of women with contraindications to the use of emergency contraceptive pills
- where the cost of an over-the-counter product may be a barrier, health care providers must be able to continue to prescribe regular oral contraceptives according to the off-label indication supported by the FDA to ensure that OTC availability does not raise new barriers to access for those women with insurance coverage of prescription contraceptive options.
- women must have access to clear, complete and accurate information about the product. Package inserts for emergency contraception products should be available in multiple languages and should employ techniques for women who cannot read such as using pictorial representations as appropriate.

The Network has produced a position paper which explains our position on this issue more fully. It is attached as an appendix to the written comments I have provided to the committee.

Consumer understanding

One the underlying principles that guides the Network's work is that informed consumers can make good health care decisions for themselves. The definition of an informed consumer, however, is critically important to the realization of this principle. We must trust people with complete information, rather than withholding details that commercial sponsors or health care professionals may fear will complicate or bias the consumer's decision. The FDA must ensure that consumers have access to unbiased information about the products that the agency regulates.

Advertisements paid for by commercial sponsors which are designed to sell a product are not adequate information sources for consumers. The need to ensure consumer access to unbiased and complete information is greatest where the advertising campaigns are most intense and the budgets are highest and that is in the area of OTC drug products. The only source of information that the vast majority of consumers have about a drug – other than an advertisement – is the information that is included on or in the product package. The information on the product label and in the patient package inserts must be carefully reviewed and assessed by the FDA to determine that it is complete, accurate and easily understood by potential users of the product.

The Network strongly supports the use of a standardized label format for OTC products with consistent categories and placement to make it easier for consumers to find the important information on a product label. The food label is an appropriate model, providing key information on products in a predictable format that makes it possible for consumers to learn how to the find the information they need easily.

One of the specific questions the FDA raised in the notice for this hearing is whether a prevention claim can "encourage ill-advised behavior." Taken in the context of microbicides, for example, we understand the agency to be asking whether the availability of products that claim to prevent (or reduce the risk of) transmission of sexually transmitted disease will lead to an increased willingness on the part of consumers to risk exposure to disease. The Network feels strongly that a product which offers partial protection and does not entirely eliminate risk can be used safely as long as clear information about risk and protection is conveyed to the consumer. In fact, in the field of contraception there are research models which demonstrate that a less efficacious product used more consistently can actually increase the level of effective protection. Products which are easier to use consistently than condoms, such as microbicides, therefore may actually be more effective in preventing the spread of STDs even if they have a lower theoretical efficacy rate than condoms.

Furthermore, we believe that this question reflects a tendency in this country to equate morality with health and an unspoken fear that making sexual activity safer will lead to an increase in immoral behavior. We believe this association is inappropriate and the fear is unfounded. Just

as the discovery of vaccines for polio, whooping cough and mumps has not led women to recklessly expose themselves and their children to infectious agents, there is no reason to expect such "ill-advised behavior" in other areas. There is no scientifically valid evidence that prevention claims lead to increased risky behavior, much less to an increased incidence of disease. The Network feels strongly that clear information can be conveyed to consumers regarding a product which offers partial protection and does not entirely eliminate risk and that consumers can make responsible and informed decisions about their behavior based on that information.

OTC Marketing System

As noted in our discussion of oral contraceptive pills and emergency contraceptive pills, the Network strongly supports the creation of a third alternative for drug distribution, such as that used in a number of other countries, where some nonprescription drug products are sold by pharmacists from behind the counter.

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Thank you again for the opportunity to speak today and to provide you with our comments. We look forward to learning about any changes the FDA proposes to make in its regulation of OTC drug products and to working with the agency to ensure that both prescription and OTC drugs are distributed and marketed in ways that support and facilitate consumers' efforts to use them safely and effectively.

APPENDIX A

NATIONAL WOMEN'S HEALTH NETWORK

Availability of Emergency Contraceptive Pills Without Prescription

There are now two emergency contraceptive pill (ECP) products available in the United States which clinicians can prescribe for women who want to prevent pregnancy after sex. One product contains combined contraceptive pills (ethinyl estradiol and norgestrel) and the second contains progestin-only (levonorgestrel) pills. Both products are currently available by prescription only.

Barriers to ECP Access

Even with two dedicated products on the market and despite national education campaigns by several reproductive health advocacy organizations, awareness of emergency contraception is still very low among women. In addition, there continue to be significant logistical barriers to obtaining emergency contraception within the 72 hour time period during which it is effective. Women often have difficulty, especially during weekends, locating and contacting a health care provider who is willing to prescribe the pills in a timely fashion. In some cases, health care providers require women seeking emergency contraception to come in for an appointment, resulting in further delays and barriers to use.

Recent studies revealing that ECPs are most effective when used within the first 24 hours following unprotected intercourse,[1] underscore the importance of eliminating barriers to use which extend the time interval between unprotected sex and the use of ECPs.

The persistence of barriers to access has led some reproductive health advocates to question whether prescription distribution of emergency contraception is necessary to ensure safe and effective use.[2] In Washington State, women can obtain emergency contraception directly from pharmacists who establish collaborative agreements with local physician providers. Research on this experience has demonstrated that pharmacist distribution holds the potential to increase women's access to emergency contraception significantly while still maintaining safe and effective use of the method.[3] Nationwide, however, pharmacist awareness of emergency contraception remains low, and much work would be needed to educate that community and build the partnerships necessary to expand access to all women through collaborative agreements like those in Washington.

Network Emergency Contraception Policy History

Since 1993, the National Women's Health Network has had an official policy supporting the use of ECPs.[4] This position was based on the Network's determination that there was sufficient evidence on the safety and effectiveness of the post-coital use of some oral contraceptives to support their use for this purpose.

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At the time that the Network took this position, the only way for a U.S. woman to get ECPs was for a health care provider to prescribe off-label use of certain brands of oral contraceptives. Recognizing that the absence of an FDA-approved, dedicated product limited both health care providers' and women's knowledge about this method, the Network recommended that information about emergency contraceptive pills be made widely available in order to help overcome the barriers to access resulting from lack of awareness.

In 1996, the Network testified at an FDA hearing in support of re-labeling appropriate oral contraceptive pills to make it clear that they can be used for emergency contraception.[5] Following that hearing, the FDA issued a statement indicating that it had determined that some combined and progestin-only oral contraceptives are safe and effective for use as emergency contraception.[6]

Since then, two dedicated emergency contraception products have been introduced to the U.S. market.

Network's Position on Distribution of ECPs Without a Prescription

In order to expand women's timely access to emergency contraception, the Network strongly supports the distribution of emergency contraceptive pills by pharmacists. In addition, recognizing that there are communities where pharmacy distribution will not resolve the barriers to access, the Network would support over-the-counter distribution of emergency contraceptive pills under the following conditions:

- **Protect the Health of Women With Contraindications.** The Network believes that, although there are no established contraindications to this short dose of hormones, women with a history of blood clots should avoid the use of the combined pill option. The label of an over-the-counter product must contain a clear and prominent warning explaining this precaution.

- **Preserve Affordable Access.** As long as it remains a prescription product, the cost of emergency contraceptive pills is covered by some insurance plans. If it is made available over-the-counter, women will have to pay the cost out of their own pockets. Following the shift to over-the-counter distribution, the prices of some products have risen, while for other products the price has dropped. It is not possible to predict with certainty what would happen to the price of emergency contraceptive products. Where the cost of an over-the-counter product may be a barrier, health care providers should continue to prescribe regular oral contraceptives according to the off-label indication supported by the FDA to ensure that OTC availability does not raise new barriers to access for those women with insurance coverage of prescription contraceptive options.

- **Provide Clear, Complete and Broadly Accessible Patient Information.** Patient package inserts for emergency contraception products should be available in multiple languages and should employ techniques for women who cannot read such as using pictorial representations as appropriate. Inserts must include a warning that if the woman is already pregnant as a result of sex which took place more than 72 hours before taking the first pills, the product will not be effective. In addition, women must be clearly informed about the failure rate of the product and necessary follow-up to determine whether a pregnancy has occurred. The insert must also inform women that emergency contraception provides no protection against sexually transmitted disease, including HIV.

Some advocates have expressed the concern that making ECPs available without a prescription might make it less likely that women using the method in cases of sexual assault will get counseling and medical follow-up. The Network supports efforts to make counseling and medical services accessible to sexual assault survivors who choose to pursue them and opposes policies which require or otherwise pressure survivors to obtain such services against the woman's own desire or will. Therefore, the Network does not believe that the prescription requirement for ECPs should be maintained in order to make it necessary for sexual assault survivors to go to a health care provider.

In light of the continued low levels of awareness of ECPS, the Network also reiterates its 1993 recommendation that all women seeking to prevent pregnancy should receive information about this contraceptive method and whether it is a safe choice for them.

Conclusion

If the concerns outlined in this position paper are adequately addressed, the Network believes the shift to over-the-counter status for ECPs would give women greater access and greater control over their use of the method without undermining safe and effective use.

In this context, it is important to note that the Network's opposition to over-the-counter distribution of oral contraceptive pills for continuing contraception remains unchanged.[7] This distinction is based on the Network's belief that the medical, political and economic issues raised by emergency contraceptive pills are different from those associated with the on-going use of oral contraceptives and that prescription status for regular oral contraceptives is necessary to protect the health of women who choose to use that method.

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